

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/526,697

Confirmation No. 9619

Applicant: Dudley et al.

Filed: May 5, 2005

TC/AU: 1644

Examiner: Michail A. Belyavskiy

Docket No.: 233876 (Client Reference No. E-275-2002/1-US-02)

Customer No.: 45733

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

We, Mark E. Dudley, Steven A. Rosenberg, and John R. Wunderlich do hereby declare as follows:

1. We are the co-inventors of the pending claims in the above-referenced patent application.
2. We conceived of and reduced to practice the claimed invention in the United States before July 2, 2001, as evidenced by the following:
 - a. attached to this Declaration is a true and accurate copy of a report prepared by Mark E. Dudley. The report summarizes research performed involving the administration of non-myeloablative lymphodepleting chemotherapy followed by adoptive transfer of autologous T cells to melanoma patients. The autologous T-cells had been previously isolated and selected for highly avid recognition of an antigen of the melanoma by stimulation of the T-cells *in vitro* with the antigen of the melanoma. In patients A, B, E, and F, this *in vitro* stimulation of the T-cells was followed by one cycle of rapid

In re Appln. of Dudley et al.
Application No. 10/526,697

expansion using irradiated allogeneic feeder cells, OKT3 antibody, and IL-2. IL-2 was subsequently administered to the patients.

3. The treatment dates of Patients A-F which have been deleted from the report are prior to July 2, 2001.

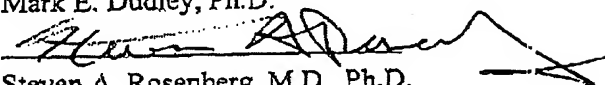
4. Each of us hereby declares that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Date: 6/3/08

Date: _____

Mark E. Dudley, Ph.D.


Steven A. Rosenberg, M.D., Ph.D.

John R. Wunderlich, M.D.

ID#	Sex	Age	Date	Cell	Age	E	MRN	Patient Characteristics		Current Status		Patient Characteristics		Other		DOD	DISEASE
								Path	Cell	Res. (mg)	Next (g)	HLA	Genotype	VX	RI		
A	Female	33.0	A	33.0	A	PR (29)	PR (29)	A02:A31	AX MT PV	10M	10M	A02:A31	AX MT PV	3	IV		
B	Female	35.0	B	35.0	B	PR (8)	PR (8)	A01:A02	SK SU	10F	10F	A01:A02	SK SU	3	IV		
C	Female	39.8	C	39.8	C	NR	NR	A02:A31	SK SU	41F	41F	A02:A31	SK SU	3	IV		
D	Female	34.0	D	34.0	D	PR (2)	PR (2)	A02:A31	SK SU	57F	57F	A02:A31	SK SU	3	IV		
E	Female	30.0	E	30.0	E	NR-M	NR-M	A02:A03	SK SU	55M	55M	A02:A03	SK SU	3	IV		
F	Female	56.5	F	56.5	F	PR (24)	PR (24)	A02:A11	SK SU PLU	37F	37F	A02:A11	SK SU PLU	3	IV		
G	Female	122.6	G	122.6	G	NR	NR	A02:A03	CE CL SU	41M	41M	A02:A03	CE CL SU	3	IV		
H	Female	94.5	H	94.5	H	NR	NR	A02:A30	SU	48M	48M	A02:A30	SU	3	IV		
I	Female	93.7	I	93.7	I	PR (12)	PR (12)	A02:A03	SK SU	57M	57M	A02:A03	SK SU	3	IV		
J	Female	169.0	J	169.0	J	PR (14)	PR (14)	A02:A0205	SK SU	55M	55M	A02:A0205	SK SU	3	IV		
K	Female	130.0	K	130.0	K	NR	NR	A02:A11	BNSU CV LIP	35M	35M	A02:A11	BNSU CV LIP	3	IV		
L	Female	137.0	L	137.0	L	NR-M	NR-M	A02:A11	BNSU GB LILU	37F	37F	A02:A11	BNSU GB LILU	3	IV		
M	Female	77.0	M	77.0	M	NR	NR	A02	SU	41F	41F	A02	SU	3	IV		

up change CR